

# Substance Abuse: A Clinical Laboratory Perspective

**Presented by:**

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# Prescription Drug Monitoring

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## Topics

- 1 National Opioid Epidemic
- 2 Clinical Drug Monitoring
- 3 Health Trends
- 4 Q&A

# National Overdose Epidemic

# Drug Misuse and Overdose Deaths

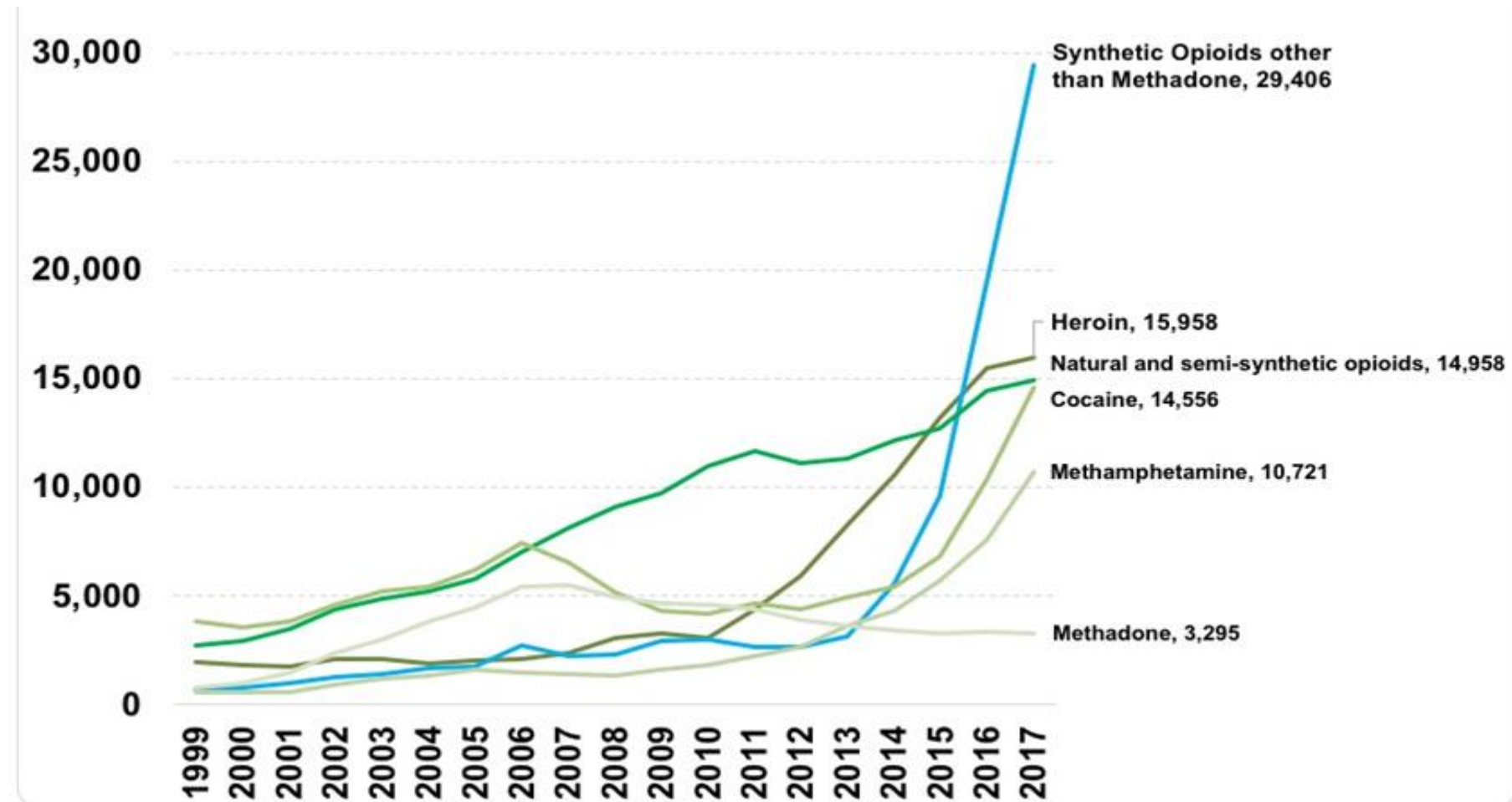
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## Understanding the epidemic

- The drug epidemic is one of the most significant and challenging healthcare issues of our time.
- 72,000 Americans died from drug overdose during 2017
- Laboratory data is foundational to healthcare and reveals trends and patterns that prescription, claims and other data cannot, both for the individual and populations.
- We provide insights into the evolving drug misuse epidemic – insights based on analysis of clinician-ordered drug monitoring performed for patients across the United States by Quest Diagnostics.

# Changing Pattern of Overdose Deaths Involving Opioids

United States, 1999 – 2017 72,000 drug overdose deaths



Source: Drug overdose death rate. NIH. <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates>

# What Has Contributed to Prescription Drug Misuse?

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Patients may unintentionally misuse prescription drugs

They may do the following:

- Fail to follow prescriber's instructions
- Underestimate the potentially addictive nature of pain medications and other controlled medications
- Assume prescription drugs are safe to use under all circumstances
- Share their prescription drugs with friends or family
- Fail to secure their medications
- Not dispose of their unused medication



# Drug Misuse Risk Screening

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Screeners tools are utilized to help detect risk of opioid misuse during opioid therapy of pain.

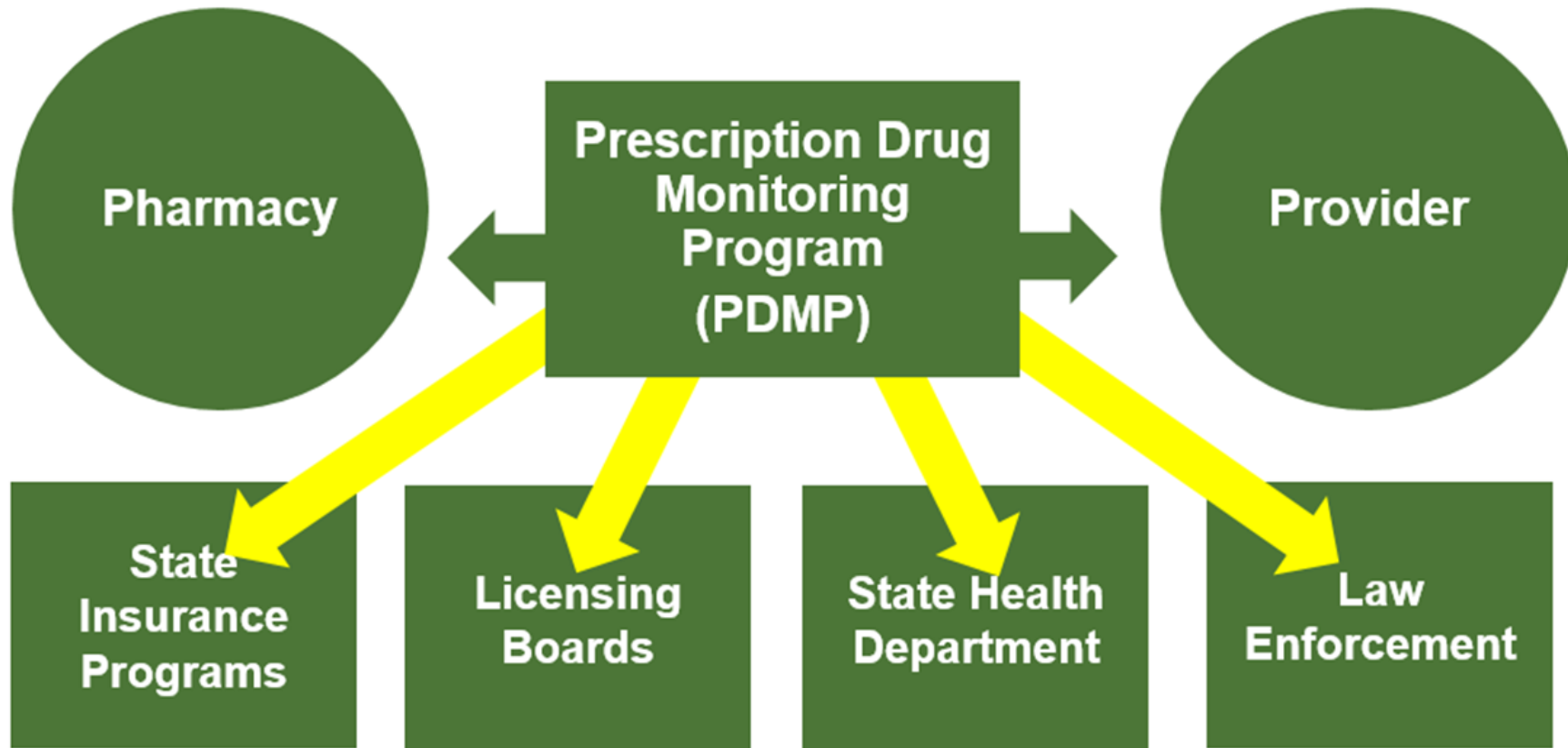
Clinical judgement required to inform practice. Examples include:

- Opioid Risk Tool (ORT)<sup>1</sup>
  - five questions
- Screener and Opioid Assessment for Patients with Pain, revised (SOAPP®-R)<sup>2</sup>
  - 24 questions
- Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression (RIOSORD)<sup>3</sup>
  - 15 questions

1. Webster LR, Webster R. Predicting aberrant behaviors in Opioid-treated patients: preliminary validation of the Opioid risk too. Pain Med. 2005; 6 (6) : 432  
2. PainEDU, Inflexiion, Inc [http://nationalpaincentre.mcmaster.ca/documents/soapp\\_r\\_sample\\_watermark.pdf](http://nationalpaincentre.mcmaster.ca/documents/soapp_r_sample_watermark.pdf)  
3. <http://paindr.com/wp-content/uploads/2015/09/RIOSORD-tool.pdf>

# Monitoring Drugs Prescribed

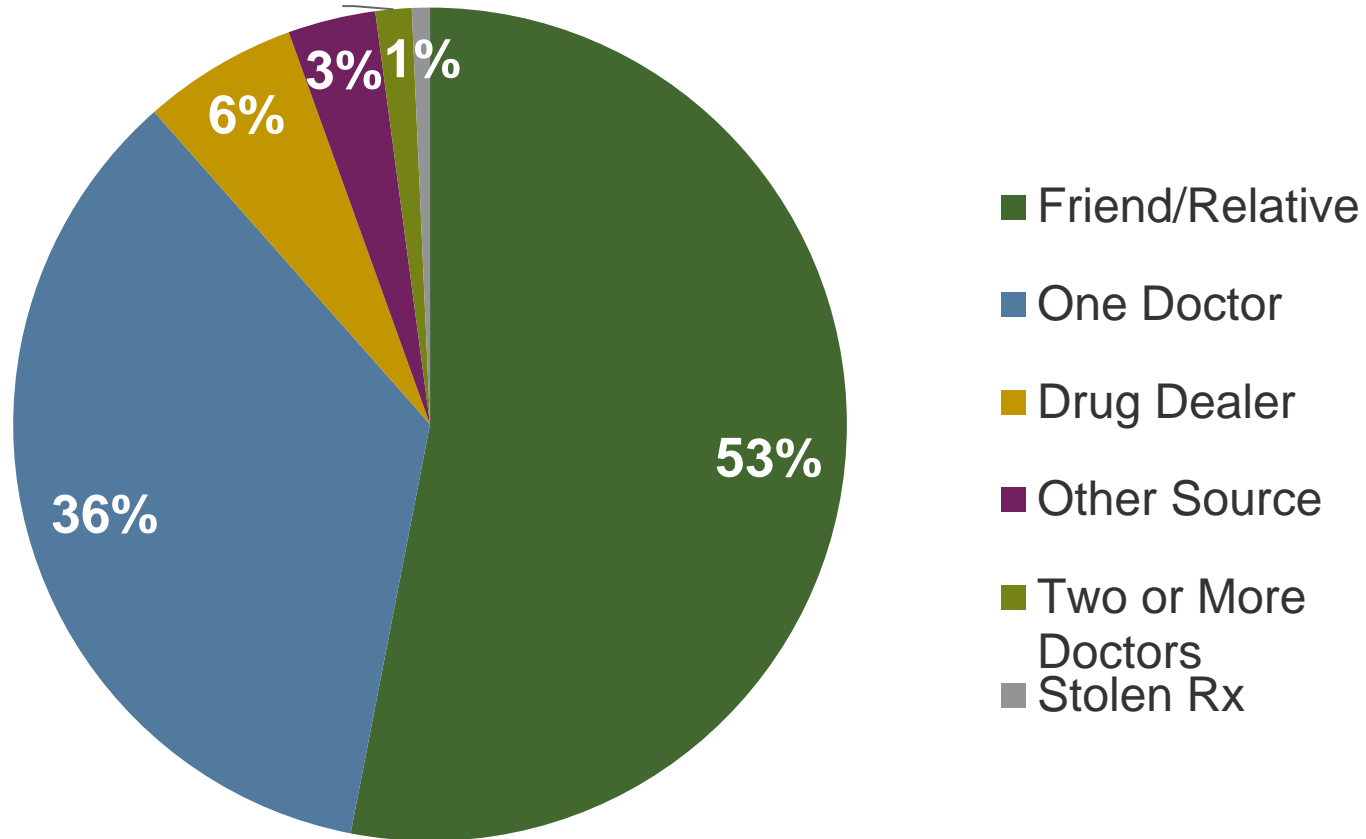
Prescription Drug Monitoring Programs (PDMPs) are among state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients.<sup>1</sup>



<sup>1</sup> *Opioid Overdose, What States Need to Know about PDMPs*. Centers for Disease Control and Prevention (CDC).. October 2017. <https://www.cdc.gov/drugoverdose/pdmp/states.html> accessed April 9 2018.

# Sources of Prescription Pain Relievers Among Misusers

2017 Percentages



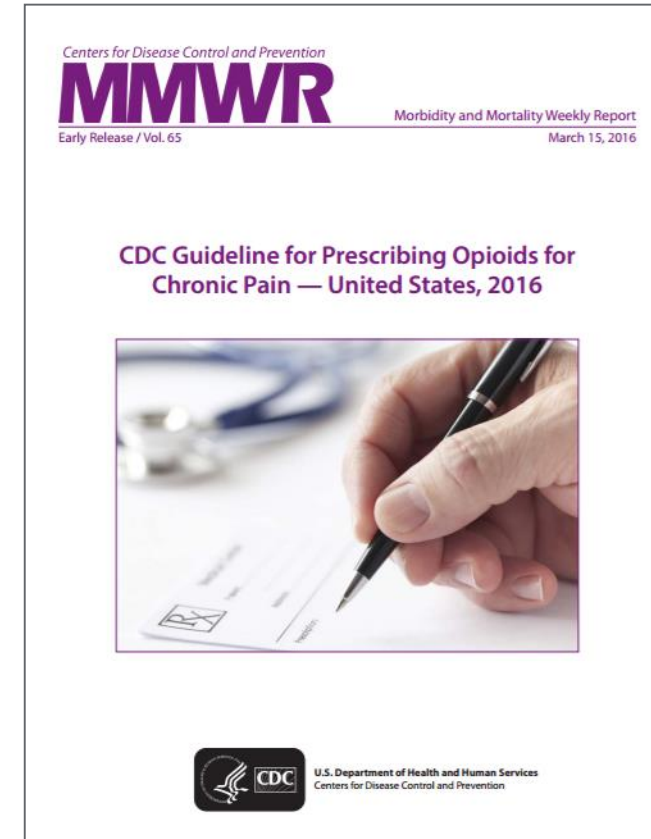
~ 53%

Obtain prescription drugs from friends and family.

# CDC Guideline for Prescribing Opioids for Chronic Pain

## First national guideline on opioid prescribing

- Released by CDC in March 2016
- 12 recommendations targeted to primary care providers
- Primary care providers account for about 50% of prescription opioids dispensed
- Excludes pain treatments for cancer pain, terminal illness, and end-of-life care



# Areas of Focus

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Start Low. Go Slow.

Determining when to initiate or continue opioids for chronic pain

Opioid selection, dosage, duration, follow-up, and discontinuation

Assessing risk and addressing harms of opioid use

# What Can Be Done at the Practice Level?

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## Clinicians can take steps to manage risk

- Evaluate risk factors for opioid-related harms
- Check PDMP for high dosages and prescriptions from other providers
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed
- Use urine drug testing to identify prescribed substances and undisclosed use



# Clinical Drug Monitoring

# Monitoring Drugs Used

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Urine drug testing is a part of a comprehensive monitoring process

Used to detect use or non-use of prescribed drugs and non-prescribed or illicit drugs. Drug detection is an objective indicator of the patient's adherence or compliance to their treatment plan. Drug testing can help to:

- Identify prescription compliance or noncompliance
- Detect use of illegal substances
- Identify potential drug-drug interaction
- Maintain patient access to prescription therapies

“When prescribing opioids for chronic pain, clinicians should use urine drug testing **before starting opioid therapy** and consider urine drug testing **at least annually** to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.”

*CDC Guideline Recommendation, 2016*

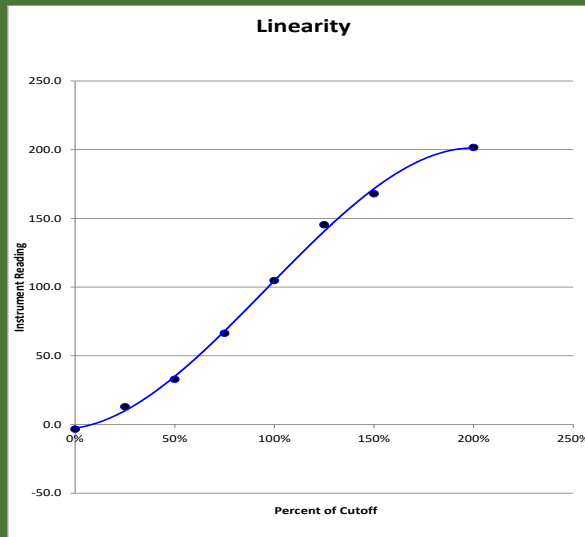
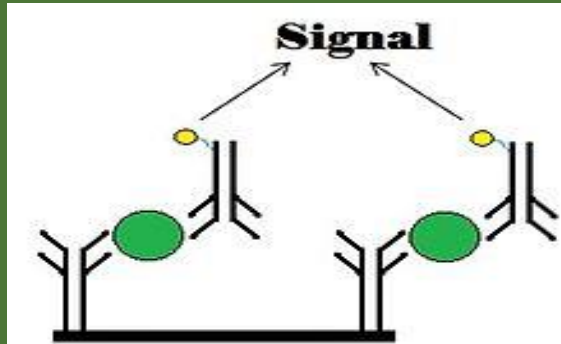
# Drug Testing Terminology

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## Qualitative, Quantitative, Presumptive and Definitive?

- Qualitative and Quantitative are obsolete terms to describe drug testing.
- Effective 2015, the American Medical Association (AMA) Current Procedural Terminology (CPT) publication defined presumptive and definitive as intuitive terms to describe drug testing for use or non-use of drugs.
- Qual and Quant are terms for which many operational definitions could apply. Some health plans have utilized Qual to describe presumptive drug testing and Quant to describe definitive testing.
- Presumptive testing is always reported qualitatively as either Negative or Presumptive Positive.
- Definitive testing can be reported qualitatively (Negative or drug/metabolite identity) or quantitatively (quantitation of drugs/metabolites).

# Presumptive Drug Testing

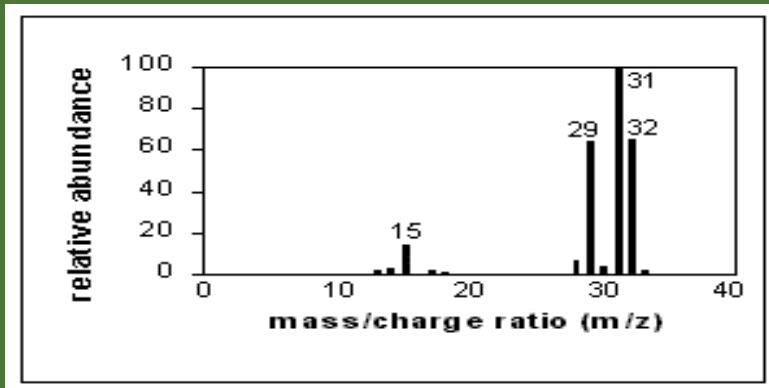


Drug test immunoassays (IA) are used to differentiate “negative” from “presumptive positive” specimens. Antibody cross reactivity to the antigen (drug/metabolites) may be broad or narrow and all results that are equal to or greater than the cutoff are considered to be “presumptive”.

Presumptive drug tests also include mass spectrometry analysis with or without chromatography.

- Presumptive tests cannot provide a definitive identification of what drug/metabolites are present, and
- False-positive results cannot be distinguished from true-positive results

# Definitive Drug Testing

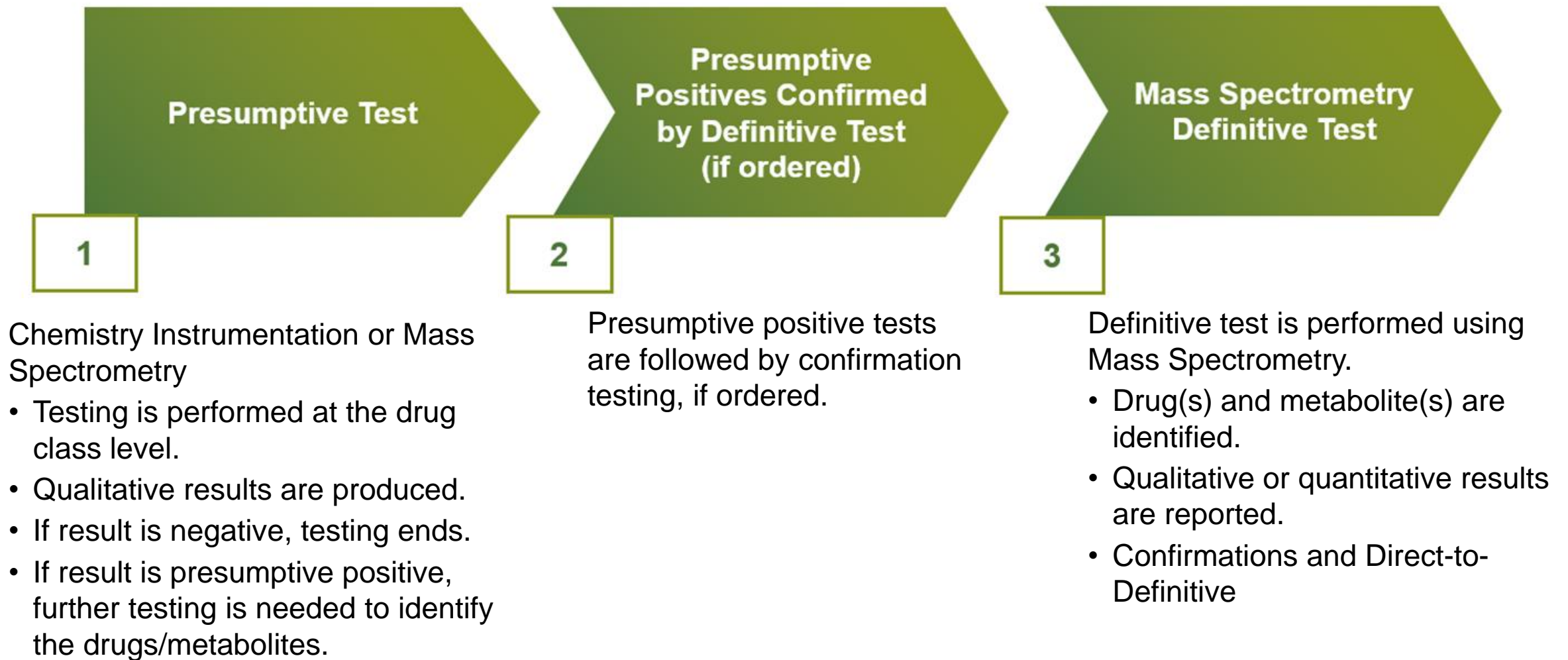


Definitive assays rule out “false-positive” results and identify “true-positive” presence of drug and/or metabolite. Contemporary methods utilize mass spectrometry coupled to chromatographic retention to identify drugs/metabolites. Examples of mass spectrometry include:.

- Liquid chromatography-tandem mass spectrometry (LC/MS/MS)
- Liquid chromatography-time of flight mass spectrometry (LC/TOF)
- Gas chromatography-mass spectrometry (GC/MS)
- Definitive tests may be qualitative or quantitative.

# Drug Testing Process 1

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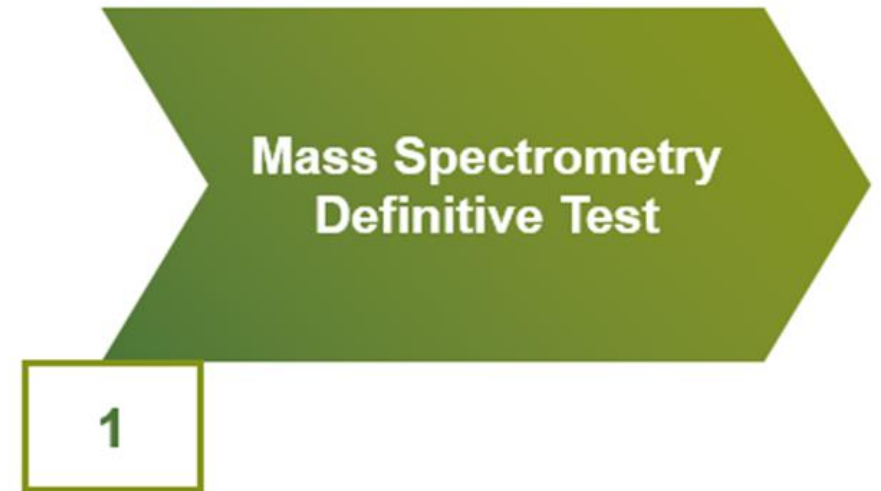


# Drug Testing Process

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## When presumptive testing is not available or insensitive?

- Definitive testing provides the only method of analysis

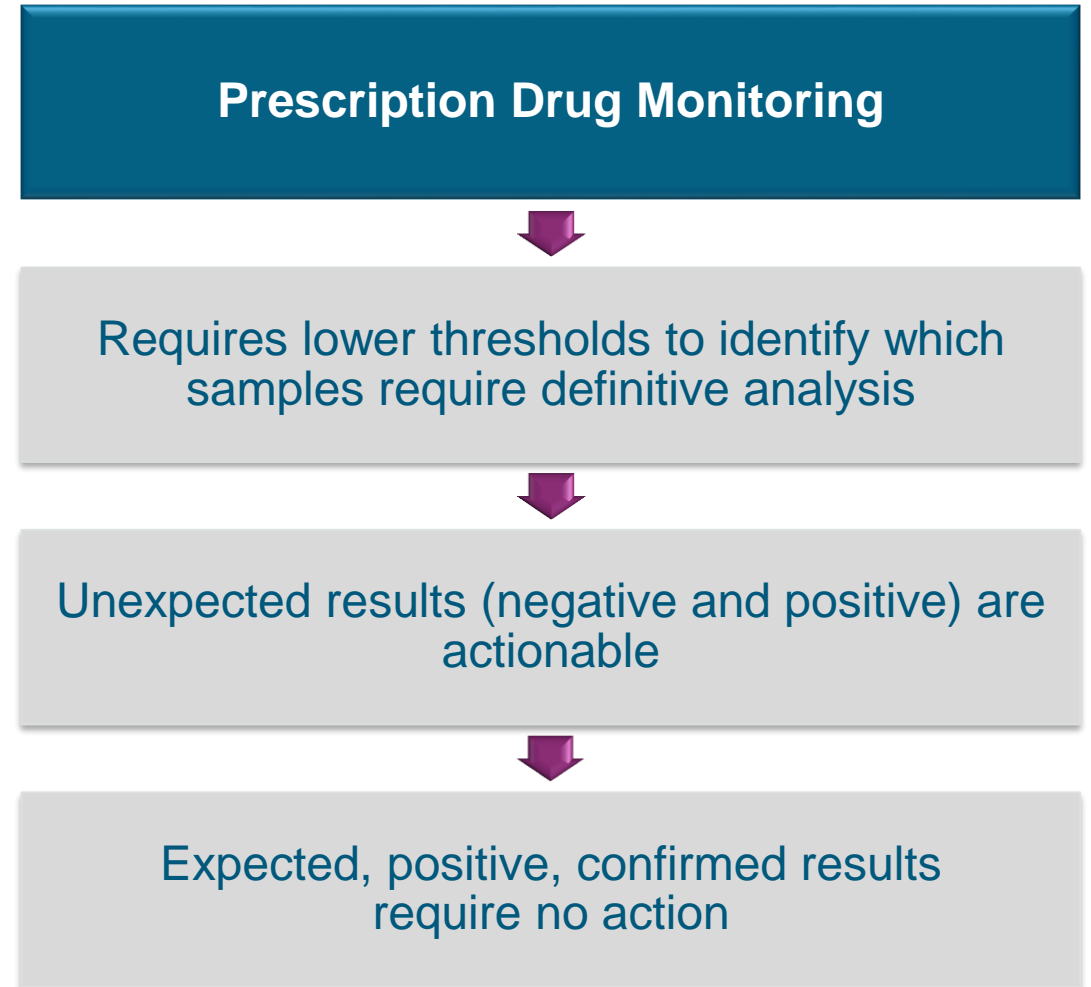
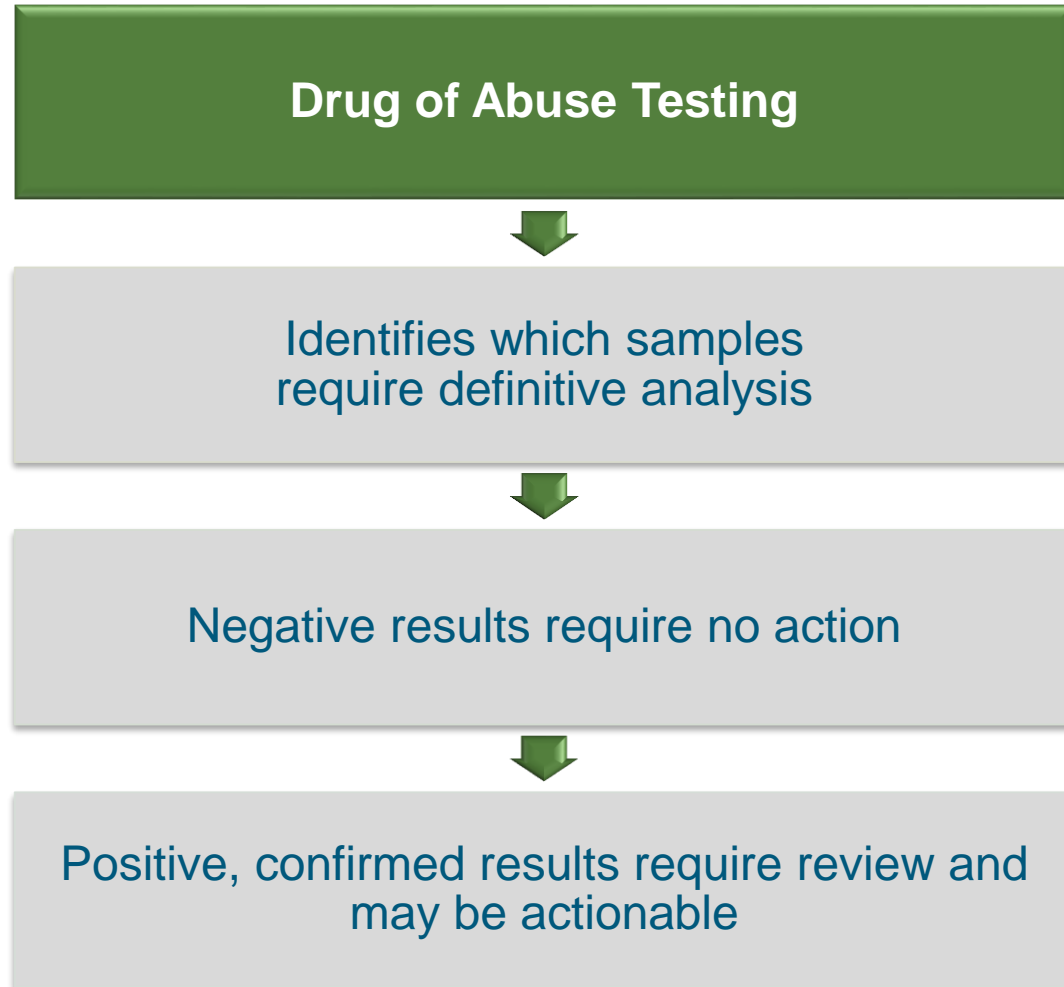


Definitive test is performed using Mass Spectrometry.

- Drug(s) and metabolite(s) are identified.
- Qualitative or quantitative results are reported.
- Confirmations and Direct-to-Definitive

# Drug Abuse Testing versus Prescription Drug Monitoring

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# Quest Diagnostics Health Trends

# Drug Test Consistency with Prescribed Drugs

Consistency rates have plateaued since 2014



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More than half of  
patients misuse  
their medications

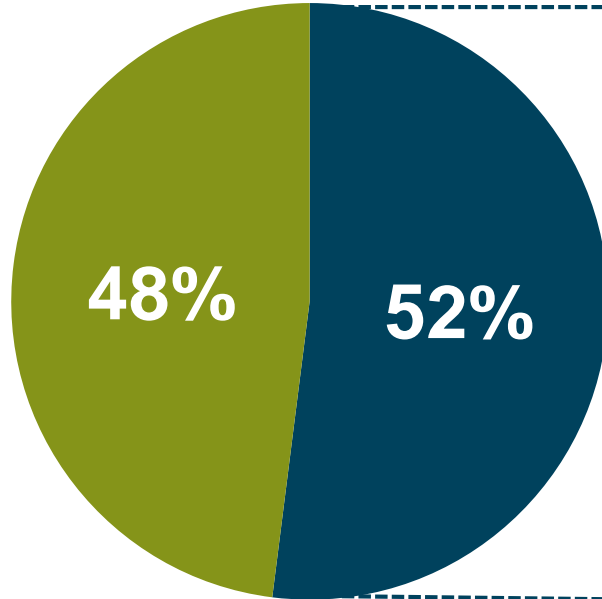
 Inconsistent



# Patients Do Not Follow Provider Instructions...

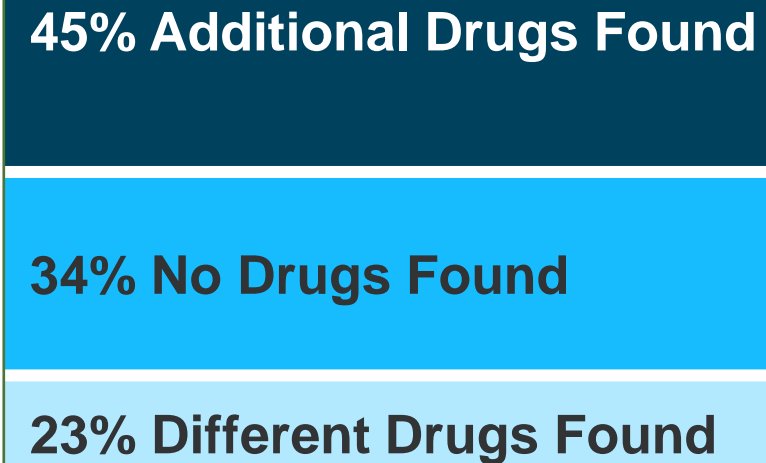
## Prescription drug monitoring results distribution

### Inconsistent vs. Consistent



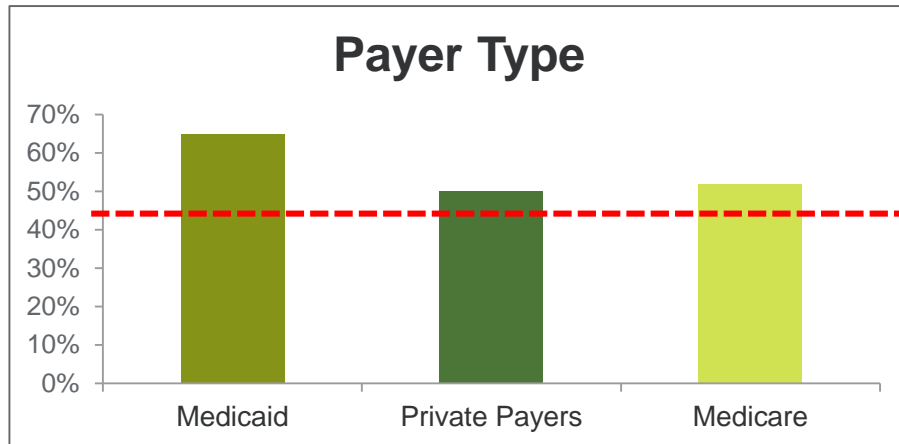
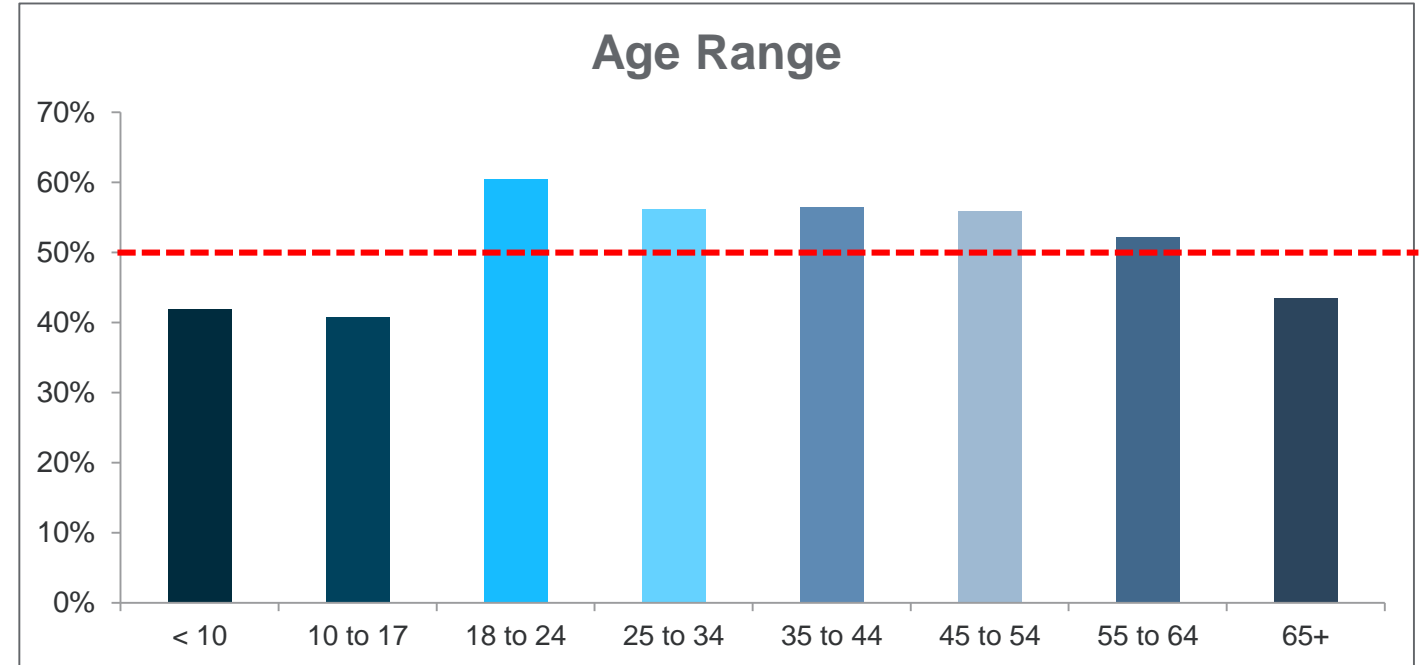
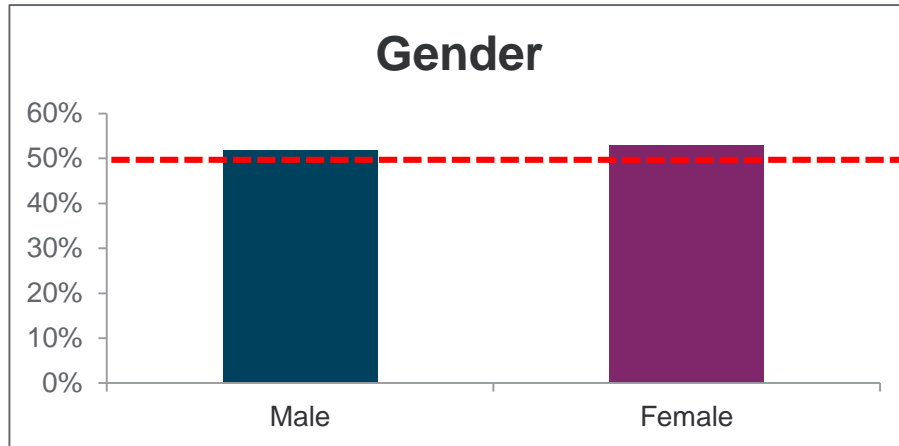
- Inconsistent
- Consistent

### Distribution of Inconsistent Results



# ...Regardless of Gender, Payer Type, or Age

## Prescription drug monitoring results distribution

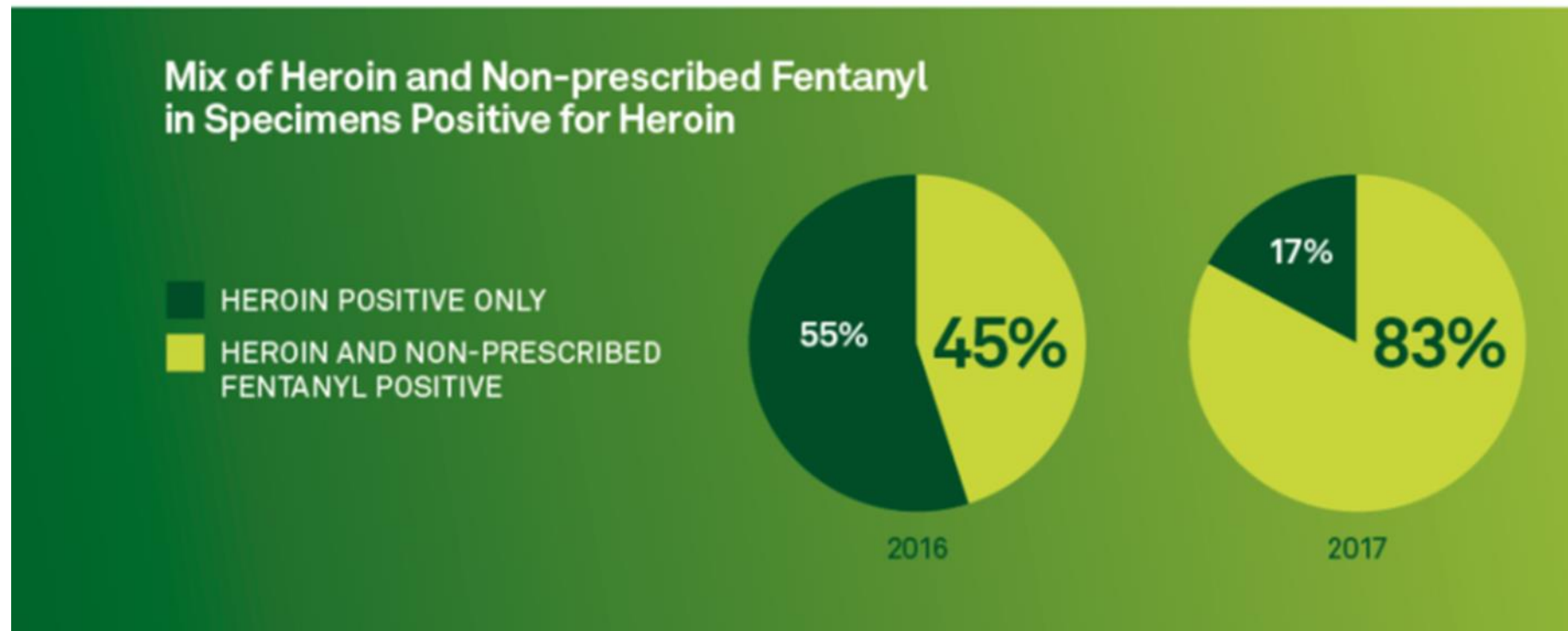


# Non-Prescribed Fentanyl and Heroin Changes

Increasing percentage from 2016 to 2017



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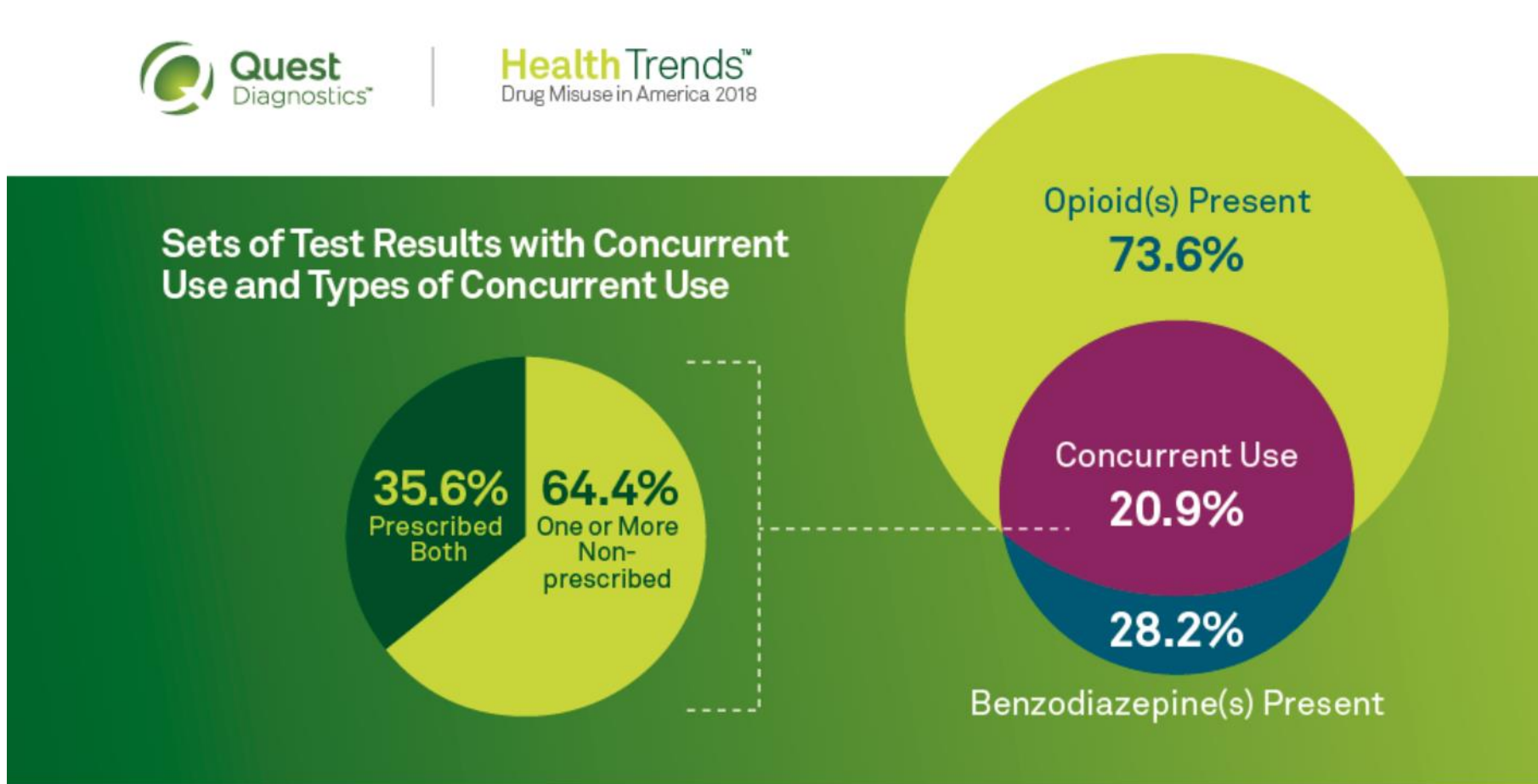


# ...Concurrent Use of Benzodiazepines with Opioids

Prescribed databases alone do not identify actual combining of drug groups



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# Questions & Answers

# CLIA Q&A

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- ***The new clinical toxicology testing programs being implemented at PHL are intended for surveillance purposes for non-fatal overdoses. How do CLIA regulations apply?***
- *CLIA requires all entities that perform even one test, including waived test on ... "materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings" to meet certain Federal requirements. If an entity performs tests for these purposes, it is considered under CLIA to be a laboratory and must register with the CLIA program."*<sup>1</sup>
- ***While intended for surveillance purposes, the testing methods may be suitable for diagnostic purposes. How is the regulatory landscape different if patient results were to be reported to healthcare providers?***
- *Regardless of the specimen types, identifying drug presence for possible use or non-use of drugs is considered 'drug testing'. Drug testing includes presumptive and definitive methods of analysis. Therapeutic drug monitoring, using blood, serum analysis, is utilized to monitor clinical outcomes and is not considered 'drug testing'.*

<sup>1</sup> [https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How\\_to\\_Apply\\_for\\_a\\_CLIA\\_Certificate\\_International\\_Laboratories.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.html) accessed October 16, 2018.

# CLIA Q&A

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- ***Most PHL are not particularly involved in drug toxicology testing. What should they keep in mind from the CLIA perspective?***
- *Appropriate CLIA licensure is required. CLIA-performed drug testing is not for forensic or legal purposes. Appropriate disclosure of test limitations (e.g., presumptive) is required for laboratory test reports. The moderately complex lab requires: director, technical consultant, clinical consultant, and testing personnel. The highly complex lab requires director, technical supervisor, general supervisor, clinical consultant, and testing personnel. Presumptive testing may be moderate or highly complex whereas definitive testing is highly complex.*
- ***How are CLIA regulations applicable to testing for novel opioids for which there might not be available standard materials?***
- *New psychoactive substances (NPS) including novel opioids requires the use of highly complex definitive testing to identify possible use or non-use of these drugs.*